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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,691	07/20/2001	Ping Gao	28341/00222.US1	9971

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,691

Applicant(s)

GAO ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-35 is/are pending in the application.
- 4a) Of the above claim(s) 21-24 and 28-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3, 6-20 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Receipt of RCE, amendment and remarks all dated 9-7-04 is acknowledged.

Claims 1-3 and 6-35 are pending. Claims 21-24 and 28-35 have been withdrawn. Claims 1-3, 6-20 and 25-27 are being examined.

Claim Rejections - 35 USC § 103

Claims 1-3, 6-20 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/03113 (WO) in view of US 6,660,286 to Lambert et al (Lambert).

Instant claims are directed to a self-emulsifying drug delivery (SEDD) system comprising an extremely water-insoluble lipophilic active agent, a fatty acid, a surfactant and polyvinylpyrrolidone (PVP), wherein the molecular weight of PVP is about 2,500 to about 20,000 and the weight ratio of fatty acid to PVP is 2:1 to 1:3. Dependent claims further limit the ratio of surfactant to PVP; recite specific surfactants, fatty acids, active agents etc.

WO '113 teaches a SEDD system for increasing bioavailability of water insoluble or oil soluble drugs, comprising the 0.1% to 17% drug, 2% to 50% of a solubilizer, 10% to 55% of an emulsifier and oil (claim 1 and pages 6-7, page 8, lines 14-24). Particularly, WO '113 teaches the claimed emulsifiers (page 7) and their solubilizers include fatty acids such as oleic acid, linoleic acid (lines bridging pages 7-8). The percentages of drug, solubilizer and surfactant taught by WO are within the claimed range. Further, WO also teaches the claimed surfactants such as polyoxyethylene glycerides (page 7). WO '113 teaches oral administration of the composition in the form of gelatin capsules (page 8, lines 25-28). WO does not teach PVP of the instant claims and also fails to teach specific drugs of claim 20. However, WO suggests that the composition

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can be used with any active agents such as protease inhibitors or other active agents (page 10).

WO further teaches addition of antioxidants such as BHA, ascorbic acid etc.

Lambert teaches emulsion vehicles for poorly soluble drugs such as paclitaxel comprising a solvent, tocopherol polyethylene glycol succinate or PEGylated TGPS, a poorly water-soluble drug, a co-solvent such as NMP or polyvinylpyrrolidone and a surfactant (col. 5). In a preferred embodiment, Lambert suggests that the co-solvent may be polyvinylpyrrolidone, or PEG or NMP (col. 5, lines 34-37). In particular, Lambert teaches PVP having a molecular weight between 2,500 and 100,000 and at a concentration of 1% to 5%, which is within claimed range (col. 3 and col. 7). Lambert suggests that using solvents and co-solvents, mentioned above, avoids the necessity of solubilizing poorly soluble active agents in monohydric alcohols and other volatile solvents, and further eliminates the need for removal of solvents prior to emulsification. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add co-solvent, PVP having a molecular weight between 2500 and 100000, in the self-emulsifying drug delivery system of WO. Further, choosing the appropriate molecular weight of PVP and the ratio of insoluble active agent to co-solvent (PVP), as well as the ratio of different co-solvents such as fatty acids (WO) and PVP (Lambert), with an expectation to successfully solubilize the poorly water-soluble active agents without the need to employ volatile solvents.

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Response to Arguments

Applicant's arguments with respect to claims 1-3, 6-20 and 25-27 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
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November 10, 2004